IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
CHARLOTTE DIVISION
CIVIL ACTION NO. 3:18-CV-00491-KDB-DCK

EMILY DENNIS, **Plaintiff,** **v.** **BAYER HEALTHCARE PHARMACEUTICALS INC., BRACCO DIAGNOSTICS, INC., BAYER CORPORATION, MCKESSON CORPORATION, and BAYER HEALTHCARE LLC,** **Defendants.**	**ORDER**

THIS MATTER is before the Court on Defendant McKesson Corporation's Motion to Dismiss Plaintiff's Amended Complaint for Failure to State a Claim Under F.R.C.P. 12(b)(6) (Doc. No. 11), Bracco Diagnostics Inc.'s Motion to Dismiss (Doc. No. 31), and the Motion to Dismiss by specially appearing Defendants Bayer Corporation, Bayer Healthcare LLC, and Bayer Healthcare Pharmaceuticals Inc. (collectively, "Bayer Defendants") (Doc. No. 44). The Court has carefully considered the motions, the parties' related briefs, the Amended Complaint (Doc. No. 8), and all other relevant portions of the record.

With due regard for the applicable standards of review of motions to dismiss pursuant to Rule 12, the Court finds that Plaintiff has, at this early stage of the case, adequately pled her claims against Bracco and the Bayer Defendants and has made a prima facie showing of personal jurisdiction over the Bayer Defendants**.** As for her claims against McKesson, the Court finds that any state claims based on a failure to warn are preempted by federal law and that Plaintiff has failed to adequately plead any other claims she has against McKesson. The Court will grant

Plaintiff's request that she be given leave to amend her complaint. Accordingly, as more fully discussed below, the Court will **GRANT** McKesson Corporation's motion to dismiss (Doc. No. 11), **DENY** Bracco Diagnostics Inc.'s motion to dismiss (Doc. No. 31), **DENY** the Bayer Defendants' motion to dismiss (Doc. No. 44), and will give Plaintiff thirty days to amend her complaint.

I. RELEVANT BACKGROUND & PROCEDURAL HISTORY

For purposes of these motions, the Court accepts as true all well-pled facts and draws all reasonable inferences in Plaintiff's favor. This matter arises out of the design, development, manufacturing, testing, packaging, promoting, marketing, advertising, distribution, labeling, and sale of two pharmaceutical drugs, Magnevist and MultiHance. (Doc. No. 8, at ¶ 2). Both drugs are gadolinium-based contrast agents ("GBCA") often used in MRIs. *Id.* Gadolinium is a highly toxic heavy metal that does not occur naturally in the human body. *Id.* at ¶ 1. The only known route for gadolinium to enter the human body is by injection of a GBCA. *Id.*

Defendant Bayer Healthcare Pharmaceuticals Inc. is the United States pharmaceuticals unit of Bayer Healthcare LLC. Bayer Corporation, Bayer Healthcare LLC, and Bayer Healthcare Pharmaceuticals Inc. are all engaged in the business of "designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing Magnevist into interstate commerce, either directly or indirectly through third parties or related entities." *Id.* at ¶¶ 18-20. Defendant Bracco Diagnostics Inc. ("Bracco") is a company that "manufactures, tests, markets, advertises, and sells" MultiHance. *Id.* at ¶¶ 20-21. Defendant McKesson Corporation ("McKesson") is a distributor of both Magnevist and MultiHance. *Id.* at ¶¶ 23-24.

Multiple studies since the 1980s have indicated that gadolinium could be retained in soft-tissue long after the date of injection of a GBCA. *Id.* at ¶¶ 43-50. Those in the scientific community

connected the administration of GBCAs to a "rapidly progressive, debilitating and often fatal condition called gadolinium-induced Nephrogenic System Fibrosis (NSF)," especially in patients with abnormal kidney function. *Id.* at ¶ 52. This prompted the Food and Drug Administration (FDA) to issue a black box warning in 2007 for all GBCAs regarding the release of toxic gadolinium and its long-term retention in patients with abnormal kidney function. *Id.* In the 2010s, it became increasingly clear that similar risks from using GCBAs existed in patients with normal kidney function. *Id.* at ¶¶ 54-56. The FDA issued a new public safety alert in 2015 indicating that it was evaluating the risk of brain deposits from repeated use of GBCAs in MRIs. *Id.* at ¶ 57. In 2017, the FDA's medical advisory committee voted to add warning labels about gadolinium retention in patients with normal kidney function. *Id.* at ¶ 58. On May 21, 2018, GBCA manufacturers issued a joint warning to medical providers stating, *inter alia*, that gadolinium may be retained for months to years in a patient's bones, brain, skin, and other organs after a GBCA injection. *Id.* at ¶ 59.

Plaintiff Emily Dennis ("Plaintiff"), a resident of North Carolina, was injected with Magnevist three times in 2014 and MultiHance once in late 2008 prior to receiving MRIs. *Id.* at ¶¶ 11-13. Plaintiff claims the gadolinium contained in Magnevist and MultiHance does not wash out of the patient's body as readily as promised, and instead can be retained indefinitely or permanently in multiple organs and soft tissues (e.g., brain, heart, liver, kidney, bones, and skin) in patients with normal renal function. *Id.* at ¶ 4. The retention of gadolinium in Plaintiff's body caused her to be diagnosed with Gadolinium Disposition Disease and other "permanent physical and emotional injuries," including fibrosis in her organs, skin, and bones and retention of gadolinium in her brain. *Id.* at ¶¶ 14-15. She claims she did not determine the cause of her injuries until December 2017

when tests revealed the continued presence of toxic levels of gadolinium in her body. *Id.* at ¶ 37. This suit followed.

Plaintiff filed her initial complaint on September 7, 2018. (Doc. No. 1). She filed an Amended Complaint on February 6, 2019 alleging diversity jurisdiction pursuant to 28 U.S.C. § 1332. (Doc. No. 8, at ¶ 5). In her Amended Complaint, she states that Defendants were aware that Magnevist and MultiHance could cause retention of toxic gadolinium in patients with normal renal function long before she was injected. She seeks compensatory and punitive damages, as well as attorneys' fees and costs. *Id.* at ¶¶ 39-50; 54-61. Plaintiff asserts that the joint warning by GCBA manufacturers in 2018 was the first time that Defendants made any effort to warn Plaintiff, her health care providers, the medical community, or the general public about the significant risks identified with the use of similar GCBAs that she was injected with. *Id.* at ¶ 61. She brings the following eight causes of action against all Defendants: (1) failure to warn; (2) negligence; (3) negligent misrepresentation; (4) negligence per se; (5) breach of express warranty; (6) breach of implied warranties; (7) fraudulent misrepresentation and concealment; and (8) civil battery. Defendants have moved to dismiss all claims against them.

II. STANDARD OF REVIEW

A. Failure to State a Claim under Rule 12(b)(6)

Under Federal Rule of Civil Procedure 8(a)(2), a complaint must contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). However, "Rule 8(a)(2) still requires a 'showing,' rather than a blanket assertion, of entitlement to relief." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 n.3 (2007).

A motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) for "failure to state a claim upon which relief can be granted" tests whether the complaint is legally and factually sufficient.

See Fed. R. Civ. P. 12(b)(6); *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009); *Bell Atlantic Corp.*, 550 U.S. at 570; *Coleman v. Maryland Court of Appeals*, 626 F.3d 187, 190 (4th Cir. 2010), *aff'd sub nom. Coleman v. Court of Appeals of Maryland*, 566 U.S. 30 (2012). In evaluating whether a claim is stated, "[the] court accepts all well-pled facts as true and construes these facts in the light most favorable to the plaintiff," but does not consider "legal conclusions, elements of a cause of action, . . . bare assertions devoid of further factual enhancement[,] . . . unwarranted inferences, unreasonable conclusions, or arguments." *Nemet Chevrolet, Ltd. v. Consumeraffairs.com, Inc.*, 591 F.3d 250, 255 (4th Cir. 2009). Construing the facts in this manner, a complaint must only contain "sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Id.* (internal quotations omitted). Thus, a motion to dismiss under Rule 12(b)(6) determines only whether a claim is stated; "it does not resolve contests surrounding the facts, the merits of a claim, or the applicability of defenses." *Republican Party of North Carolina v. Martin*, 980 F.2d 943, 952 (4th Cir. 1992).

Ordinarily, a plaintiff need only make "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). However, with respect to claims of fraud, Rule 9(b) creates an exception to this liberal pleading standard and requires that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). "This heightened pleading requirement serves to protect defendants' reputations from baseless accusations, eliminate meritless suits brought only to extract a settlement, discourage fishing expeditions, and provide defendants with enough information about a plaintiff's allegations to mount a defense." *Maguire Fin., LP v. PowerSecure Int'l, Inc.*, 876 F.3d 541, 546 (4th Cir. 2017) (citing *Pub. Emps.' Pub. Employees' Ret. Ass'n of Colo. v. Deloitte & Touche LLP*, 551 F.3d 305, 311 (4th Cir. 2009)).

B. Personal Jurisdiction

When personal jurisdiction is properly challenged under Rule 12(b)(2), the burden is on the plaintiff ultimately to prove the Court's jurisdiction over the defendants by a preponderance of the evidence. *Carefirst of Maryland, Inc. v. Carefirst Pregnancy Centers, Inc.*, 334 F.3d 390, 396 (4th Cir. 2003). However, "when the court addresses the personal jurisdiction question by reviewing only the parties' motion papers, affidavits attached to the motion, supporting legal memoranda, and the allegations in the complaint, a plaintiff need only make a prima facie showing of personal jurisdiction to survive the jurisdictional challenge." *Grayson v. Anderson*, 816 F.3d 262, 268 (4th Cir. 2016). In deciding whether the plaintiff has made the requisite showing, the Court must construe all allegations and evidence available relating to the issue of personal jurisdiction in the light most favorable to the plaintiff. *Id.*

Rule 4 of the Federal Rule of Civil Procedure prescribes that state law controls the extent to which a federal court may exercise personal jurisdiction over a defendant. Fed. R. Civ. P. 4(k)(1)(A). Accordingly, North Carolina's Long Arm Statute, N.C. Gen. Stat. Ann. § 1-75.4, governs the reach of federal courts in North Carolina over out-of-state defendants, subject to the federal constitutional constraints of the Due Process Clause of the Fourteenth Amendment on the state's application of its long-arm statute. *Goodyear Dunlop Tires Operations, S.A. v. Brown*, 564 U.S. 915, 923 (2011). Courts have long held, however, that North Carolina's long-arm statute extends to the maximum boundaries allowed by the Due Process Clause; therefore, what would otherwise be a two-step analysis, *English & Smith v. Metzger*, 901 F.2d 36, 38 (4th Cir. 1990), essentially folds into one: "whether the defendant has such 'minimal contacts' with the forum state that 'maintenance of the suit does not offend traditional notions of fair play and substantial

justice.'" *Christian Sci. Bd. of Directors of First Church of Christ, Scientist v. Nolan*, 259 F.3d 209, 215 (4th Cir. 2001) (quoting *Int'l Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945)).

To establish minimum contacts, a plaintiff may pursue either general or specific jurisdiction. *ALS Scan, Inc. v. Digital Serv. Consultants, Inc.*, 293 F.3d 707, 711–12 (4th Cir. 2002). To establish general jurisdiction, the defendant's activities in the state must have been "continuous and systematic." *Id.* If specific jurisdiction is alleged, the court exercises its power over a defendant when defendant's contacts within the state are the basis of the plaintiff's cause of action. *Id.*

In analyzing the contacts for specific jurisdiction, courts "consider (1) the extent to which the defendant 'purposefully avail[ed]' itself of the privilege of conducting activities in the State; (2) whether the plaintiffs' claims arise out of those activities directed at the State; and (3) whether the exercise of personal jurisdiction would be constitutionally 'reasonable.'" *Id.*; *see Helicopteros Nacionales de Colombia, S.A. v. Hall*, 466 U.S. 408, 414 & n.8 (1984). In conducting this inquiry, the Court must focus on "the quality and nature of the [relevant contacts]." *Nichols v. G.D. Searle & Co.*, 783 F. Supp. 233, 238 (D. Md. 1992), *aff'd*, 991 F.2d 1195 (4th Cir. 1993). The Court should not "merely [ ] count the contacts and quantitatively compare this case to other preceding cases." *Id.* Even a single contact may be sufficient to create jurisdiction when the cause of action arises out of that single contact, provided that the principle of "fair play and substantial justice" is not thereby offended. *Id.* (citing *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 477–78 (1985)). In the Fourth Circuit, a plaintiff "cannot rely simply upon the 'stream of commerce' logic to establish jurisdiction" over a defendant "that delivers its products into the stream of commerce with the expectation that they will be purchased in the forum State." *Lesnick v. Hollingsworth & Vose Co.*, 35 F.3d 939, 946 (4th Cir. 1994) (internal quotations omitted).

III. DISCUSSION

Defendants raise a number of challenges to Plaintiff's claims, mainly that she failed to state claims upon which relief can be granted under 12(b)(6). The Court will address each Defendant's motion in turn. First, the Court will address McKesson's motion to dismiss for failure to state a claim. Then, the Court will address Bracco's motion to dismiss for failure to state a claim, and lastly, will turn to the Bayer Defendants' motion to dismiss for lack of personal jurisdiction and failure to state a claim.

"[F]ederal courts sitting in diversity apply state substantive law and federal procedural law." *Gasperini v. Ctr. for Humanities, Inc.*, 518 U.S. 415, 427 (1996); *see also Erie R. Co. v. Tompkins*, 304 U.S. 64, 78 (1938). In this products liability suit, Plaintiff alleges that she was "at all relevant times a resident and citizen of the State of North Carolina." (Doc. No. 8, at ¶ 11). A reasonable inference from this statement is that she was injected with Magnevist and MultiHance while in North Carolina. Therefore, Plaintiff's substantive claims are governed by North Carolina law.[1]

A. McKesson's Motion to Dismiss

McKesson argues that the Amended Complaint should be dismissed with prejudice because Plaintiff's allegations fail to meet the pleading standards under *Bell Atlantic Corporation*, 550 U.S. 544, and *Iqbal*, 556 U.S. 662. With respect to Plaintiff's claims for negligent misrepresentation and fraudulent misrepresentation and concealment, McKesson argues the Amended Complaint does not satisfy the heightened pleading requirements under Federal Rule of Civil Procedure 9(b).

[1] While Defendants claim that Plaintiff's Amended Complaint should be dismissed because she fails to allege where the injections happened, they do not contest that North Carolina law applies.

McKesson's main argument is that Plaintiff's Amended Complaint is not specific enough because it lumps the Defendants together and fails to make distinctions among Defendants' actions. (Doc. No. 11-1, at 9). McKesson contends that because it is a pharmaceutical distributor, it plays a different role than a manufacturer of Magnevist or MultiHance. *Id.* The liability of a distributor, McKesson purports, turns on a showing that the distributor manufactured, sold, supplied, or was in some way responsible for the product alleged to have caused Plaintiff's injuries. *Id.* at 12 (citing *In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Relevant Prod. Liab. Litig.*, No. 3:09-CV-20003, 2010 WL 3937414, at *5 (S.D. Ill. Oct. 4, 2010). McKesson argues Plaintiff cannot plausibly allege that it was in some way responsible for Plaintiff's injuries because it was preempted from varying the language of the FDA-approved pharmaceutical labeling.

Despite more expansive allegations set forth within the complaint, Plaintiff agrees in its response brief that McKesson is not a manufacturer of either drug, but instead a distributor or seller of the drugs. Under North Carolina law, "[n]o manufacturer or seller of a product shall be held liable in any product liability action for a claim based upon inadequate warning or instruction unless the claimant proves that the manufacturer or seller acted unreasonably in failing to provide such warning or instruction." N.C. Gen. Stat. Ann. § 99B-5(a). The Supreme Court in *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 613–15 (2011), held that generic drug manufacturers cannot be held liable for state failure-to-warn claims because federal drug law does not allow generic manufacturers to unilaterally change a drug label—a conflict that preempts state law. Numerous courts have determined that drug distributors, like generic manufacturers, lack the power to change warning labels under federal law and thus cannot be liable for state failure-to-warn claims. *See, e.g., Smith v. GE Healthcare, Inc.*, No. 3:19-CV-00492, 2019 WL 4565246, at *7–9 (W.D. La. Sept. 4, 2019); *Pierik v. GE Healthcare Inc.*, No. 1:18-CV-07733, 2019 WL 4686551, at *1–2

(N.D. Ill. June 18, 2019); *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prod. Liab. Litig.*, No. 2:14-CV-01810, 2016 WL 7644792, at *2–3 (D.S.C. Nov. 28, 2016) ("[T]he Court holds that the claims against McKesson based on Lipitor's label are clearly preempted by federal law."); *In re Fosamax (Alendronate Sodium) Prod. Liab. Litig. (No. II)*, No. MDL 2243 JAP-LHG, 2012 WL 181411, at *3 (D.N.J. Jan. 17, 2012).

Plaintiff responds that other courts have found McKesson a viable defendant in pharmaceutical drug products liability cases. Yet, one case Plaintiff cites, *In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Prod. Liab. Litig.*, 779 F. Supp. 2d 846 (S.D. Ill. 2011), was decided before the Supreme Court's decision in *Mensing* and that same court later applied *Mensing* to determine that failure-to-warn claims against a drug distributor were preempted. *In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Prod. Liab. Litig.*, No. 309MD02100DRHPMF, 2014 WL 1632149, at *10 (S.D. Ill. Apr. 24, 2014). The other cases Plaintiff cites to in support of its argument that McKesson is a proper defendant permit claims against drug distributors that are unrelated to failure-to-warn claims and FDA-approved labels.

The Court agrees with McKesson that "Plaintiff cannot allege that McKesson acted unreasonably in its failure to provide a warning because, under federal FDA regulations, McKesson had no authority to create or modify the FDA-approved label of Magnevist or MultiHance." (Doc. No. 50, at 2). Because federal law will not permit McKesson to do what state law purports to require of it, Plaintiff's incompatible state law claims are preempted. Thus, the Court grants McKesson's motion to dismiss to the extent Plaintiff seeks to hold it liable for failing

to warn Plaintiff of the risks or defects of Magnevist or MultiHance. Plaintiff's claims for failure to warn, negligent misrepresentation, and breach of express warranty are dismissed.[2]

As to Plaintiff's remaining claims, the Court finds that Plaintiff has failed to plead sufficient factual allegations that specify what actions by McKesson allegedly violated the law. In fact, it is unclear if Plaintiff's remaining claims are premised on a failure-to-warn or some other action by McKesson. For example, Plaintiff's fraudulent misrepresentation and concealment claim mentions Bracco and the Bayer Defendants multiple times, but fails to mention McKesson by name or specify what false statements McKesson may have made that harmed Plaintiff.

Plaintiff requests leave to amend her complaint if the Court finds that her allegations are insufficiently pled. Pursuant to Federal Rule of Civil Procedure 15(a), which provides that the Court should freely grant leave to amend "when justice so requires," the Court finds it appropriate to allow Plaintiff to file a second amended complaint to address these deficiencies. This case is still in the early stages of the proceedings and granting Plaintiff leave to amend will not cause McKesson prejudice. Given that this will be Plaintiff's second amended complaint, it is unlikely the Court will give Plaintiff another chance to amend in the future absent extenuating circumstances. Accordingly, if Plaintiff chooses to amend her complaint a second time, she should ensure that all her claims are supported by factual allegations.

[2] Plaintiff asserts that preemption is not a question the Court should resolve on a motion to dismiss. (Doc. No. 26, at 5-6). The Court disagrees. Because it is clear from the face of the Amended Complaint that McKesson is a distributor and that Magnevist and MultiHance are FDA-approved products, the question of preemption can be decided at the motion to dismiss phase. *See Franklin Livestock, Inc. v. Boehringer Ingelheim Vetmedica, Inc.*, 113 F. Supp. 3d 834, 837 (E.D.N.C. 2015) ("The affirmative defense of preemption may be resolved on a motion to dismiss, provided the facts necessary to determine the issue clearly appear on the face of the complaint."); *Horne v. Novartis Pharm. Corp.*, 541 F. Supp. 2d 768, 783 (W.D.N.C. 2008) (dismissing failure-to-warn and inadequate labeling claims at the motion to dismiss phase in a pharmaceutical products liability case because they were preempted).

B. Bracco's Motion to Dismiss

Defendant Bracco asserts three arguments as to why Plaintiff's Amended Complaint should be dismissed. First, Bracco moves to dismiss Plaintiff's claims under Rule 12(b)(6) for "fail[ing] to plausibly allege an injury, causation, and that the injury was reasonably foreseeable to [Bracco] at the time that Plaintiff's prescribing physician administered MultiHance to the Plaintiff." (Doc. No. 32, at 1-2). Second, Bracco contends that the applicable statute of limitations bar Plaintiff's claims. (Doc. No. 32, at 2). Third, Bracco argues Plaintiff has failed to satisfy the heightened pleading requirements set forth in Federal Rule of Civil Procedure 9(b) and the lesser pleading requirements under Rule 8.

1. Injury, Causation, and Reasonable Foreseeability

The Court finds that Plaintiff has plausibly pled a cognizable injury. Plaintiff alleges that the tissues in her body and her brain have retained gadolinium, which has resulted in "permanent physical and emotional injuries" and fibrosis in her soft tissues. (Doc. No. 8, at ¶¶ 14-15, 32, 34-36). To the extent Plaintiff claims her injury is gadolinium retention and other injuries that are a result of gadolinium retention, Plaintiff has sufficiently pled causation. *See Goodell v. Bayer Healthcare Pharm. Inc.*, No. 18-CV-10694-IT, 2019 WL 4771136, at *1–6 (D. Mass. Sept. 30, 2019) (concluding the plaintiff had sufficiently pled causation in a case with nearly identical facts); *Pierik,* 2019 WL 4686551, at *2 ("Causation can be inferred from the FDA's recent actions regarding GBCAs and the scientific studies plaintiffs cite."). Bracco's argument that gadolinium retention is not an injury prematurely challenges the merits of Plaintiff's claims. Whether gadolinium retention is an injury or whether there is any causal link between gadolinium deposition and any disease cannot be resolved on the pleadings. Bracco's dispute over the reasonable foreseeability of Plaintiff's alleged injuries are also premature on a motion to dismiss.

Plaintiff alleges in her Complaint that Bracco was aware of the risk gadolinium presented to patients with normal kidney function, yet continued to manufacture it and failed to alert patients or medical providers of the risk. She cites to specific articles, journals, and other information that she claims made this injury foreseeable. (Doc. No. 8, at ¶¶ 39-57). With due regard for the applicable standards of review of motions to dismiss, the Court finds Plaintiff has sufficiently pled injury, causation, and foreseeability.

2. Statute of Limitations

The parties agree that Plaintiff's claims have a three-year statute of limitations, pointing to North Carolina General Statute Section 1-52. Plaintiff argues that she did not discover, and through reasonable care and due diligence could not have discovered, that she had claims against Defendants related to her gadolinium retention until she was diagnosed with Gadolinium Disposition Disease in December 2017.

For fraud claims, a plaintiff is required to file within three years of her "discovery . . . of the facts constituting the fraud." N.C. Gen. Stat. Ann. § 1-52(9). "Discovery" means either "actual discovery or when the fraud should have been discovered in the exercise of reasonable diligence." *State Farm Fire & Cas. Co. v. Darsie*, 589 S.E.2d 391, 396 (N.C. Ct. App. 2003). For negligence-based claims, a cause of action for personal injury or physical property damage "shall not accrue until bodily harm to the claimant or physical damage to his property becomes apparent or ought reasonably to have become apparent to the claimant, whichever event first occurs." N.C. Gen. Stat. Ann. § 1-52(16). In cases involving disease, North Carolina courts have held that a cause of action does not accrue until the disease is diagnosed. *See, e.g.*, *Earp v. Novartis Pharm. Corp.*, No. 5:11-CV-680-D, 2013 WL 4854488, at *5 (E.D.N.C. Sept. 11, 2013) ("In the case of diseases, [North Carolina's] limitations period does not begin until a medical diagnosis reveals the nature of

plaintiff's disease."); *Wilder v. Amatex Corp.*, 336 S.E.2d 66, 72 (N.C. 1985) ("The only possible point in time from which to measure the 'first injury' in the context of a disease claim is when the disease is diagnosed."). Viewing the evidence in the light most favorable to Plaintiff, her Gadolinium Deposition Disease was not diagnosed until December 2017. (Doc. No. 8, at ¶¶ 14, 34). She did not discover any potential claims against Defendants until that time. Because she filed suit on September 7, 2019, less than three years after December 2017, her claims are timely.

3. Pleading Standards

Bracco's motion to dismiss is denied with respect to Plaintiff's fraud and negligent misrepresentation claims. Allegations of fraud are subject to a heightened pleading standard that generally requires a plaintiff to plead the "who, what, where, when, why, and how" of the fraud. *Rohlik v. I-Flow Corp.*, No. 7:10-CV-173-FL, 2011 WL 2669302, at *3 (E.D.N.C. July 7, 2011); Fed. R. Civ. P. 9(b). These heightened requirements apply equally to a claim for negligent misrepresentation. *Topshelf Mgmt., Inc. v. Campbell-Ewald Co.*, 117 F. Supp. 3d 722, 727 (M.D.N.C. 2015) ("Federal courts have repeatedly found that the North Carolina tort of negligent misrepresentation sounds in fraud and have applied Rule 9(b)[.]").

Plaintiff meets this standard at this early stage. She pleads the dates on which she was injected with MultiHance (Doc. No. 8, at ¶ 13) and that she was in North Carolina when those injections occurred (Doc. No. 8, at ¶ 11). She also alleges how Bracco falsely represented that the gadolinium in MultiHance was eliminated from the body and does not cross the blood-brain barrier when Bracco knew that the gadolinium in those drugs is retained in the body and brain for long periods of time. (Doc. No. 8, at ¶¶ 4, 39, 40, 51). These allegations are sufficient to survive a motion to dismiss. *See Pierik*, 2019 WL 4686551, at *2 (denying manufacturers' motion to dismiss claims for fraud in nearly identical circumstances).

Bracco asserts that Plaintiff's negligence per se, breach of express warranty, breach of implied warranty, and civil battery are deficient under *Twombly* and *Iqbal*. Bracco's motion to dismiss as to these claims is denied. These claims are not subject to any heightened pleading standard and need only be set out in a "short and plain statement" that shows Plaintiff is entitled to relief. Fed. R. Civ. P. 8(a)(2); *ACA Fin. Guar. Corp. v. City of Buena Vista, Virginia*, 917 F.3d 206 (4th Cir. 2019). Plaintiff has done that with respect to her remaining claims against Bracco for negligence per se, breach of express warranty, breach of implied warranty, and civil battery. However, if Plaintiff has more factual allegations to support her claims against Bracco, she is encouraged to include them if she chooses to amend her complaint.

C. The Bayer Defendants' Motion to Dismiss

The Bayer Defendants move to dismiss on the grounds that the Amended Complaint lacks factual allegations demonstrating personal jurisdiction, Plaintiff's claims are preempted, and that Plaintiff fails to state a cognizable claim.

1. Personal Jurisdiction

First, the Bayer Defendants argue that Plaintiff fails to establish personal jurisdiction by relying on the legally defunct "stream of commerce" jurisdictional theory—a claim that Magnevist reached North Carolina because the Bayer Defendants sold it in the national marketplace through a third-party distributor.

Plaintiff does not argue that general jurisdiction applies, but she contends that she has pled sufficient facts to make a prima facie case for specific jurisdiction. The Amended Complaint references that the Bayer Defendants introduced Magnevist into interstate commerce, thereby "purposefully avail[ing] itself of the benefits and protections of this state's laws, and Plaintiff's claim arises out of Defendant's forum related activities." (Doc. No. 8, at ¶¶ 18-20). Plaintiff further

alleges that McKesson—the Bayer Defendants' distributor—does significant business in North Carolina, and that all Defendants "are authorized to do business in the District of North Carolina and derive substantial income from doing business in this state." (Doc. No. 8, at ¶¶ 24, 26). Plaintiff also states that "[u]pon information and belief, Defendants purposefully availed themselves of the privilege of conducting activities within the District of North Carolina, thus invoking the benefits and protections of its laws." (Doc. No. 8, at ¶ 27).

In support of its position, the Bayer Defendants cite to *Lesnick v. Hollingsworth & Vose Co.*, 35 F.3d 939, 946 (4th Cir. 1994). Unlike the defendant in *Lesnick*, however, the Bayer Defendants do not claim that they directed no marketing effort or other activities towards North Carolina. Moreover, the defendant in *Lesnick* made less than one percent of its income from its third-party distributor's sale of its products in the state in which the plaintiff brought the action. *Lesnick*, 35 F.3d at 946. The Bayer Defendants do not claim that only a small portion of their income comes from North Carolina. When the case is at such an early stage in the proceedings, it is hard to expect a plaintiff to have information about a company's jurisdiction beyond what is alleged by Plaintiff in her Amended Complaint. For that reason, the Bayer Defendants' motion to dismiss is denied at this time, but without prejudice to raise this issue again when there is more evidence in the record. If Plaintiff has more information regarding this Court's jurisdiction over the Bayer Defendants, she is encouraged to include it if she chooses to further amend her complaint.

2. Preemption

Second, the Bayer Defendants contend that Plaintiff's claims are preempted because they could not unilaterally change Magnevist's FDA-approved label and that clear evidence shows that the FDA would have rejected Plaintiff's desired warning had the Bayer Defendants added it using the CBE regulation. Accordingly, the Bayer Defendants contend that they may not be held responsible

under state law for wrongdoing that is effectively the result of the federal regulatory scheme within which it must operate. Plaintiff responds that the preemption analysis begins with a presumption against preemption, and that she has sufficiently alleged that the Bayer Defendants were aware of newly acquired evidence that would allow the unilateral addition of a different warning and that there is not clear evidence that the FDA would have refused to change the label.

The CBE regulation "permits drug manufacturers to change a label to 'reflect newly acquired information' if the changes 'add or strengthen a . . . warning' for which there is 'evidence of a casual association,' without prior approval from the FDA." *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1679 (2019) (internal citations omitted). Indeed, it is "a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times." *Wyeth v. Levine*, 555 U.S. 555, 570–71 (2009). This includes not only the requirement that the manufacturer craft an adequate label, but also "ensuring that its warnings remain adequate as long as the drug is on the market." *Id.* at 571. The manufacturer's ability to make changes under the CBE regulation is, however, not plenary; the changes must be based on "newly acquired information" and, in relevant part, be to "add or strengthen a contraindication, warning, precaution, or adverse reaction for which the evidence of a causal association satisfies the standard for inclusion in the labeling." 21 C.F.R. § 314.70; 21 C.F.R. § 314.70(c)(6)(iii). Furthermore, the FDA is empowered to reject labelling changes made under the CBE regulation. *See* 21 C.F.R. §§ 314.70(c)(6), (7). Accordingly, absent "clear evidence" that the FDA would not have approved a change to the label, courts should not find that federal preemption foreclosed amendments to the label under the CBE regulation. *Wyeth*, 555 U.S. at 571. As a result of the CBE regulation, "a drug manufacturer will not ordinarily be able to show that there is an actual conflict between state and

federal law such that it was impossible to comply with both." *Merck Sharp & Dohme Corp.*, 139 S. Ct. at 1679.

Plaintiff does cite in her Amended Complaint to newly acquired information that arose after the FDA's approval of Magnevist's label and before Plaintiff was administered Magnevist in 2014. This includes a 2013 Japanese study finding toxic brain retention of GBCAs in patients with normal renal functions and a 2014 autopsy study of 13 deceased individuals performed by the Mayo Clinic, which found significant levels of gadolinium within the individuals' brains. (Doc. No. 8, at ¶¶ 55-56). The Mayo Clinic study is what led the FDA to issue a public safety alert related to retained gadolinium in July 2015. (Doc. No. 8, at ¶ 57). *Cf. Goodell*, 2019 WL 4771136, at *4 (dismissing the plaintiff's claims based on inadequate label on preemption grounds because the complaint was void of "allegations that Bayer has new information . . . that it could have or should have amended the label pursuant to the CBE regulation"); *McGrath v. Bayer HealthCare Pharm. Inc.*, 393 F. Supp. 3d 161, 168 (E.D.N.Y. 2019) (dismissing plaintiff's failure-to-warn claims as preempted because plaintiff's allegations did not state a plausible claim that, at the relevant time, Bayer knew or should have known of new information indicating a causal association between exposure to Magnevist and a the risk of retention in patients with normal renal function). Whether or not the FDA would have rejected the label requested is not something that can be decided on the pleadings. Therefore, at this time, the Bayer Defendants' motion to dismiss on preemption grounds is denied. [3]

[3] The Bayer Defendants move to dismiss any design defect claims on preemption grounds, but Plaintiff concedes that it makes no design defect claims. (Doc. No. 55, at 12).

3. Pleading Standards

Lastly, the Bayer Defendants purport that Plaintiff's claims do not suffice under North Carolina law or federal pleading standards. Specifically, the Bayer Defendants assert that Plaintiff has not alleged a legally cognizable injury, that her vague allegations of fraud and negligent misrepresentation do not satisfy Rule 9, and her other claims do not satisfy the requirements under Rule 8. These challenges to Plaintiff's complaint were also asserted in Bracco's motion to dismiss. For the same reasons the Court denied Bracco's motion to dismiss, the Court denies the Bayer Defendants' motion to dismiss on these grounds.

IV. ORDER

IT IS THEREFORE ORDERED that:

1. McKesson's Motion to Dismiss (Doc. No. 11) is **GRANTED.** Plaintiff's claims against McKesson based on a failure to warn are **DISMISSED WITH PREJUDICE**. Plaintiff's other claims against McKesson that are not based on a failure to warn are **DISMISSED WITHOUT PREJUDICE**;
2. Bracco's Motion to Dismiss (Doc. No. 31) is **DENIED**;
3. The Bayer Defendants' Motion to Dismiss (Doc. No. 44) is **DENIED**; and
4. Plaintiff's request to amend her complaint is **GRANTED.** Plaintiff will have thirty (30) days after the issuance of this Order to amend her complaint.

Signed: February 3, 2020

Kenneth D. Bell
United States District Judge